# EPIDEMIOLOGY BULLETIN

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Recommendation of the Immunization Practices Advisory Committee

# POLIOMYELITIS PREVENTION

This revised ACIP recommendation on poliomyelitis prevention addresses issues important in poliomyelitis control in the United States today. Specifically, situations that constitute increased risk are defined, and alternatives for protection are outlined. Recommendations for immunization of adults are presented, clarifying the role of inactivated polio vaccine in immunizing adults. These recommendations also address the problems of interrupted immunization schedules and completion of primary immunization. Oral polio vaccine remains the vaccine of choice for primary immunization of children.

#### INTRODUCTION

Poliovirus vaccines, used widely since 1955, have dramatically reduced the incidence of poliomyelitis in the United States. The annual number of reported cases of paralytic disease declined from more than 18,000 in 1954 to an average annual number of less than 13 in 1973-1980. The risk of poliomyelitis is generally very small in the United States today, but epidemics are likely to occur if the immunity of the population is not maintained by immunizing children beginning in the first year of life. Small outbreaks have occurred in 1970, 1972, and 1979 as a result of introduction of virus into susceptible populations in communities with low immunization levels.

As a result of the Childhood Immunization Initiative efforts 1977-1979, immunization levels in children are now higher than ever before. The School Enterer Assessments in kindergarten and first-grade levels have indicated that the percentage of these children who have completed primary vaccination against poliomyelitis reached 95% in the 1980-1981 school year. Immunization levels in preschool children and in those who are in higher grades may be substantially lower than the levels at school entry.

Laboratory surveillance of enteroviruses shows that the circulation of wild polioviruses has diminished markedly. Inapparent infection with wild strains no longer contributes significantly to establishing or maintaining immunity, making universal vaccination of infants and children even more important.

# **POLIOVIRUS VACCINES**

Two types of poliovirus vaccines are currently licensed in the United States: Oral Polio Vaccine (OPV) and Inactivated Polio Vaccine (IPV).

# Oral Pollo Vaccine (OPV) (Official name: Poliovirus Vaccine, Live, Oral, Trivalent)

Within several years after it was licensed in the United States in 1963, trivalent OPV, the live attenuated vaccine combining all 3 strains of poliovirus, almost totally supplanted the individual monovalent OPV antigens used earlier. Full primary vaccination with OPV will produce long-lasting immunity to all 3 poliovirus types in more than 95% of recipients. Most recipients are protected after a single dose.

OPV consistently induces intestinal immunity that provides resistance to reinfection with polioviruses. Administration of OPV may interfere with simultaneous infection by wild polioviruses, a property which is of special value in epidemic-control campaigns. In rare instances (once in approximately 3.2 million doses distributed), OPV has been associated with paralytic disease in vaccine recipients or their close contacts. In the 12-year period 1969-1980, approximately 290 million doses of OPV were distributed, and 92 cases of paralysis associated with vaccine were reported. Twenty-five cases of paralysis occurred in otherwise healthy vaccine recipients, 55 cases in healthy close contacts of vaccine recipients, and 12 cases in persons (recipients or contacts) with immune-deficiency conditions.

# Inactivated Polio Vaccine (IPV) (Official name: Poliomyelitis Vaccine)

Licensed in 1955, IPV has been used extensively in this country and many other parts of the world. It is given by subcutaneous injection. Where extensively used, IPV has brought about a great reduction in paralytic poliomyelitis cases. Approximately 428 million doses have been administered in the United States, mostly before 1962. Although IPV has not been widely used in this country for more than a decade, a Canadian product licensed for use in the United States is now available.

It is generally accepted that primary vaccination with 4 doses of IPV produces immunity to all 3 poliovirus types in more than 95% of recipients. Additional experience with the IPV product available since 1968 is necessary to establish whether the duration of immunity is comparable to that induced by OPV. Experience in other countries forms the basis for the present recommendations on booster doses.

There is considerable evidence from epidemiologic studies that immunizing with IPV diminishes circulation of wild poliovirus in the community, although it is known that persons vaccinated with IPV can subsequently be infected with and excrete in feces either wild strains or attenuated vaccine virus strains. No paralytic reactions to IPV are known to have occurred since the 1955 cluster of poliomyelitis cases caused by vaccine that contained live polioviruses that had escaped inactivation. Serious adverse reactions are not anticipated with the current IPV product.

An improved IPV product with higher potency has been developed in Europe. Studies in Africa and Europe have revealed essentially 100% seroconversion following 2 doses. Duration of protection is under study. Preliminary studies are now under way in a U.S. population to compare this product with OPV.

#### **ROUTINE IMMUNIZATION**

#### Rationale for Choice of Vaccine

Although IPV and OPV are both effective in preventing poliomyelitis, OPV is the vaccine of choice for primary immunization of children in the United States when the benefits and risks for the entire population are considered. OPV is preferred because it induces intestinal immunity, is simple to administer, is well accepted by patients, results in immunization of some contacts of vaccinated persons, and has a record of having essentially eliminated disease associated with wild polioviruses in this country. The choice of OPV as the preferred polio vaccine in the United States has also been made by the Committee on Infectious Diseases of the American Academy of Pediatrics (1) and a special expert committee of the Institute of Medicine, National Academy of Sciences (2).

Some poliomyelitis experts contend that greater use of IPV in the United States for routine vaccination would provide continued control of naturally occurring poliovirus infections and simultaneously reduce the problem of OPV-associated disease. They argue that there is no substantial evidence that OPV and currently available IPV differ in their ability to protect individuals from disease. They question the public health significance of higher levels of gastrointestinal immunity achieved with OPV, and they question whether the transmission of vaccine virus to close contacts contributes substantially to the level of immunity achieved in the community.

Some countries successfully prevent poliomyelitis with IPV. However, because of many differences between these countries and the United States, particularly with respect to risks of exposure to wild polioviruses and the ability to achieve and maintain very high vaccination rates in the population, their experiences with IPV may not be directly applicable here.

Prospective vaccinees or their parents should be made aware of the polio vaccines available and the reasons why recommendations are made for giving specific vaccines at particular ages and under certain circumstances. Furthermore, the benefits and risks of vaccines for individuals and the community should be stated so that vaccination is carried out among persons who are fully informed.

## RECOMMENDATIONS FOR INFANTS, CHILDREN, AND ADOLESCENTS

#### Primary Immunization (Table 1)

OPV: For infants, children, and adolescents through secondary school age (generally up to age 18) the primary series of OPV consists of 3 doses. In infancy the primary series is integrated with DTP vaccination, and the first dose is commonly given at 6-12 weeks of age. At all ages the first 2 doses should be separated by at least 6, and preferably 8, weeks. The third dose is given at least 6 weeks, customarily 8-12 months, after the second dose. In high-risk areas, an additional dose of OPV is often given with the first 6 months of life. Breast feeding does not interfere with successful immunization.

IPV: The primary series consists of 4 doses of vaccine; volume and route of injection are specified by the manufacturer. In infancy, the primary schedule is usually integrated with DTP vaccination, as with OPV. Three doses can be given at 4- to 8-week intervals; the fourth dose should follow 6-12 months after the third.

All children should complete primary immunization before entering school, preferably with all OPV or all IPV. If, however, a combination of IPV and OPV is used, a total of 4 doses constitutes a primary series.

## Supplementary Immunization

OPV: Before entering school, all children who previously received primary immunization with OPV (3 doses) in early childhood should be given a fourth dose. However, if the third primary dose is administered on or after the fourth birthday, a fourth (supplementary) dose is not required. The additional dose will increase the likelihood of complete immunity in the small percentage of children who have not previously developed serum antibodies to all 3 types of polioviruses. The need for supplementary doses after 4 doses of OPV has not been established, but children considered to be at increased risk of exposure to poliovirus (as noted below under RECOMMENDATIONS FOR ADULTS) may be given a single additional dose of OPV.

IPV: Before entering school, all children who previously received primary immunization with either IPV alone or a combination of IPV and OPV (a total of 4 doses) in early childhood should be given at least 1 dose of OPV or 1 additional dose of IPV. However, if the fourth primary dose is administered on or after the fourth birthday, a fifth (supplementary) dose is not required at school entry. Use of a primary series of OPV would eliminate the need for subsequent booster doses of IPV.

Children who received primary immunization with IPV should obtain a booster dose of IPV every 5 years until the age of 18 years, unless a primary series of OPV is given. The need for such supplementary doses after the 5 basic doses of the currently available IPV product has not been firmly established. Further experience may lead to alteration of this recommendation.

#### Children Incompletely Immunized

Polio vaccination status should be reevaluated periodically, and those who are inadequately protected should complete their immunizations.

OPV: To help assure seroconversion to all 3 serotypes of poliovirus, completion of the primary series of 3 doses of OPV is recommended. Time intervals between doses longer than those recommended for routine primary immunization do not necessitate additional doses of vaccine. Individuals who received only 1 dose of each of the monovalent OPVs in the past should receive 2 doses of trivalent OPV at least 6 weeks apart. One dose of each monovalent OPV (poliovirus types 1, 2, and 3) is at least equivalent to 1 dose of trivalent OPV.

IPV: Regulations for vaccine licensure adopted since 1968 require a higher potency IPV than was previously manufactured. Four doses of IPV administered after 1968 are considered a complete primary series. As with OPV, time intervals between doses longer than those recommended for routine primary immunization do not necessitate additional doses.

Incompletely immunized children who are at increased risk of exposure to poliovirus (as noted below under RECOM-MENDATIONS FOR ADULTS) should be given the remaining required dose or, if time is a limiting factor, at least a single dose of OPV.

TABLE 1. Routine pollomyelitis immunization schedule summary, 1981\*

Dose	OPV age/interval	IPV age/interval				
Primary 1	Initial visit, preferably 6-12 weeks of age	Initial visit, preferably 6-12 weeks of age				
Primary 2	Interval of 6-8 weeks	Interval of 4-8 weeks				
Primary 3	Interval of 4-8 weeks					
Primary 4		Interval of 6-12 months				
Supplementary 4-6 years of age† (school entry)		4-6 years of age† (school entry)				
	with the avoid vaccin illing program of the control	and some supplier				
Additional supplementary		Interval of every 5 years				

<sup>\*</sup>Important details are in the text.

†If the third primary dose of OPV is administered on or after the fourth birthday, a fourth (supplementary) dose is not required. If the fourth primary dose of IPV is administered on or after the fourth birthday, a fifth (supplementary) dose is not required at school entry.

§Supplementary doses are recommended every 5 years after the last dose until the 18th birthday or unless a complete primary series of OPV has been completed.

### RECOMMENDATIONS FOR ADULTS

Routine primary poliovirus vaccination of adults (generally those 18 years old or older) residing in the United States is not necessary. Most adults are already immune and also have a very small risk of exposure to poliomyelitis in the United States. Immunization is recommended for certain adults who are at greater risk of exposure to wild polioviruses than the general population, including:

- 1. travelers to areas or countries where poliomyelitis is epidemic or endemic;
- 2. members of communities or specific population groups with disease caused by wild polioviruses;
- 3. laboratory workers handling specimens which may contain polioviruses;
- 4. health-care workers in close contact with patients who may be excreting polioviruses.

For individuals in the above categories, polio vaccination is recommended as detailed below.

#### **Unvaccinated Adults**

at increased risk.

For adults at increased risk of exposure to poliomyelitis, primary immunization with IPV is recommended whenever this is feasible. IPV is preferred because the risk of vaccine-associated paralysis following OPV is slightly higher in adults than in children. Three doses should be given at intervals of 1-2 months; a fourth dose should follow 6-12 months after the third.

In circumstances where time will not allow at least 3 doses of IPV to be given before protection is required, the following alternatives are recommended:

- If less than 8, but more than 4, weeks are available before protection is needed, 2 doses of IPV should be given at least 4 weeks apart.
- If less than 4 weeks are available before protection is needed, a single dose of OPV is recommended.In both instances, the remaining doses of vaccine should be given later at the recommended intervals, if the person remains

## **Incompletely Immunized Adults**

Adults who are at increased risk of exposure to poliomyelitis and who have previously received less than a full primary course of OPV or IPV should be given the remaining required doses of either vaccine, regardless of the interval since the last dose and the type of vaccine previously received.

#### Adults Previously Given a Complete Primary Course of OPV or IPV

Adults who are at increased risk or exposure to poliomyelitis and who have previously completed a primary course of OPV may be given another dose of OPV. The need for further supplementary doses has not been established. Those adults who previously completed a primary course of IPV may be given a dose of either IPV or OPV. If IPV is used exclusively, additional doses may be given every 5 years, but their need also has not been established.

# UNIMMUNIZED OR INADEQUATELY IMMUNIZED ADULTS IN HOUSEHOLDS IN WHICH CHILDREN ARE TO BE GIVEN OPV

Adults who have not been adequately immunized against poliomyelitis with OPV or IPV are at a very small risk of developing OPV-associated paralytic poliomyelitis when children in the household are given OPV. About 4 such cases have occurred annually among contacts since 1969, during which time about 24 million doses of OPV were distributed yearly. (See ADVERSE REACTIONS).

Because of the overriding importance of ensuring prompt and complete immunization of the child and the extreme rarity of OPV-associated disease in contacts, the Committee recommends the administration of OPV to a child regardless of the poliovirus-vaccine status of adult household contacts. This is the usual practice in the United States. The responsible adult should be informed of the small risk involved. An acceptable alternative, if there is strong assurance that ultimate, full immunization of the child will not be jeopardized or unduly delayed, is to immunize adults according to the schedule outlined above before giving OPV to the child.

#### PRECAUTIONS AND CONTRAINDICATIONS

#### Pregnancy

Although there is no convincing evidence documenting adverse affects of either OPV or IPV on the pregnant woman or developing fetus, it is prudent on theoretical grounds to avoid vaccinating pregnant women. However, if immediate protection against poliomyelitis is needed, OPV is recommended.

#### **Immunodeficiency**

Patients with immune-deficiency diseases, such as combined immunodeficiency, hypogammaglobulinemia and agammaglobulinemia, should not be given OPV because of their substantially increased risk of vaccine-associated disease. Furthermore, patients with altered immune states due to diseases such as leukemia, lymphoma, or generalized malignancy, or with immune systems compromised by therapy with corticosteroids, alkylating drugs, antimetabolites, or radiation should not receive OPV because of the theoretical risk of paralytic disease. OPV should not be used for immunizing immunodeficient patients and their household contacts; IPV is recommended. Many immunosuppressed patients will be immune to polioviruses by virtue of previous immunization or exposure to wild-type virus at a time when they were immunologically competent. Although these persons should not receive OPV, their risk of paralytic disease is thought to be less than that of naturally immunodeficient individuals. Although a protective immune response to IPV in the immunodeficient patient cannot be assured, the vaccine is safe and some protection may result from its administration. If OPV is inadvertently administered to a household-type contact of an immunodeficient patient, close contact between the patient and the recipient of OPV should be avoided for approximately 1 month after vaccination. This is the period of maximum excretion of vaccine virus. Because of the possibility of immunodeficiency in other children born to a family in which there has been 1 such case, OPV should not be given to a member of a household in which there is a family history of immunodeficiency until the immune status of the recipient and other children in the family is documented.

#### **ADVERSE REACTIONS**

OPV

!n rare instances, administration of OPV has been associated with paralysis in healthy recipients and their contacts. Other than efforts to identify persons with immune-deficiency conditions, no procedures are currently available for identifying persons likely to experience such adverse reactions. Although the risk of vaccine-associated paralysis is extremely small for vaccinees and their susceptible, close, personal contacts, they should be informed of this risk.

IPV

No serious side effects of currently available IPV have been documented. Since IPV contains trace amounts of streptomycin and neomycin, there is a possibility of hypersensitivity reactions in individuals sensitive to these antibiotics.

# CASE INVESTIGATION AND EPIDEMIC CONTROL

Each suspected case of poliomyelitis should prompt an immediate epidemiologic investigation, including an active search for other cases. If evidence implicates wild poliovirus and there is a possibility of transmission, a vaccination plan designed to contain spread should be developed. If evidence implicates vaccine-derived poliovirus, no vaccination plan need be developed, as no outbreaks associated with vaccine virus have been documented to date. Within an epidemic area, OPV should be provided for all persons over 6 weeks of age who have not been completely immunized or whose immunization status is unknown, with the exceptions noted above under Immunodeficiency.

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